

Appl. No. 10/011,860

Amdt. dated December 17, 2004

Reply to Office Action of September 22, 2004

### REMARKS

Applicants have received and carefully reviewed the Office Action mailed September 22, 2004. Claims 1-69 remain pending. Reconsideration and reexamination are respectfully requested.

Applicants would like to thank the Examiner for initialing and returning PTO Form 1449 which accompanied the June, 2004, Information Disclosure Statement.

As illustrated above, Applicants have amended a number of the claims for the purpose of clarity. In particular, ranges have been more specifically recited as illustrated in claim 58, which is amended as follows:

58. (Currently Amended) The method of claim 55, wherein the anti-bradycardia pacing energy comprises a monophasic waveform having a pulse width that is between approximately 20 milliseconds and ~~[[to]]~~ approximately 30 milliseconds.

Thus, pulse width is given as falling within a range. Voltage, tilt, and pulse width recitations have been amended in like fashion for claims 1-11, 13, 15, 17-27, 29, 31, 33-43, 45, 47, 49-59, 61 and 63. It is believed that these amendments do not affect the scope of the defined invention for the purposes of patentability searching and will not necessitate changing the grounds of rejection of any amended claim.

In paragraph 2 of the Office Action, claims 1-8, 12-13, 15-24, 28-29, 31-40, 44-45, 47-56, 60-61 and 63-69 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,978,703 to Kroll et al. In paragraph 4 of the Office Action, claims 9-11, 14, 25-27, 30, 41-43, 46, 57-59, and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kroll et al. Applicants address these rejections together for the purpose of brevity, as like reasoning applies to each rejection.

In particular, Applicants note that Kroll et al. do not teach or imply an anti-bradycardia pacing device using, in particular, any of the voltage or time ranges recited in the above claims. Instead, Kroll et al. teach a system wherein the application of increased voltages to the heart is used to actually cause, by direct response of the muscle to electrical signal, contraction of the heart. For example, Kroll et al. state:

An electrical method and apparatus for stimulating cardiac cells causing contraction to force hemodynamic output during fibrillation, hemodynamically

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compromising tachycardia, or asystole. High level electrical fields are applied to the heart to give cardiac output on an emergency basis until the arrhythmia ceases or other intervention takes place. The device is used as a stand alone external or internal device, or as a backup to an ICD, atrial defibrillator, or an anti-tachycardia pacemaker. The method and apparatus maintain some cardiac output and not necessarily defibrillation.

(Kroll et al., Abstract, emphasis added). Thus, contraction is forced over top of then occurring fibrillation, without necessarily ending defibrillation.

Next, Kroll et al. state:

The invention relates to the field of therapies for cardiac arrhythmias, and more particularly, to a method and an apparatus for forcing cardiac output by delivering a pulsatile electrical field to the heart during fibrillation or a hemodynamically compromising tachycardia.

(Kroll et al. at column 1, lines 14-18). Again, Kroll et al. refer to forcing cardiac output during fibrillation or tachycardia.

Kroll et al. later note:

The invention provides an electrical method of stimulating cardiac cells causing contraction to force hemodynamic output during fibrillation, hemodynamically compromising tachycardia, or asystole. Forcing fields are applied to the heart to give cardiac output on an emergency basis until the arrhythmia ceases or other intervention takes place. The device is usable as a stand alone external or internal device or as a backup to an ICD, atrial defibrillator, or an anti-tachycardia pacemaker.

The goal of the invention is maintaining some cardiac output and not necessarily defibrillation. The method is referred to as Electrical Cardiac Output Forcing and the apparatus is the Electrical Cardiac Output Forcer (ECOF).

In the implantable embodiment, a forcing field is generated by applying approximately 50 volts to the heart at a rate of approximately 100-180 beats per minute. These fields are applied after detection of an arrhythmia and maintained for up to several hours. This will generate a cardiac output which is a fraction of the normal maximum capacity. The heart has a 4 or 5 times reserve capacity so a fraction of normal pumping activity will maintain life and consciousness.

(Kroll et al. at column 1, line 65, to column 2, line 19). Indeed, Kroll et al. go so far as to distinguish pacing, for example:

Insofar as is known, no prior attempts have been made at forcing pulses during any type of fibrillation. Some workers in the field have experimented for research purposes with local pacing during fibrillation. For example, Kirchhof did local pacing during atrial fibrillation in dog hearts (Circulation 1993; 88:736-

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749). He used 0.5 mm diameter electrodes and pacing stimuli. As expected, small areas around the heart were captured but no pumping action was expected or detected. Similar results have been obtained in the ventricle by KenKnight (Journal of the American College of Cardiology 1994; 283A).

(Kroll et al. at column 2, lines 31-41). Thus, pacing is distinct from an attempt to force pulsative movement. In particular, pacing requires "capture", which is distinct from "forcing" insofar as capture indicates an artificially initiated yet self propagating contraction, instead of a fully coerced contraction of the muscle.

It appears that the Kroll et al. device is designed to assure continued cardiac output during cardiac distress (either fibrillation or tachycardia). In essence, an electrical form of a chest compression is applied. As noted, individual applied stimulations are not designed nor specifically intended to perform a pacing function. Instead, the heart is electrically forced to contract.

A pacing stimulus, in contrast, is applied for the purpose of prompting the heart's own electrical system to function. The goal of pacing capture is to provide a pulse sufficient to trigger a self-propagating depolarization wave through the patient's heart. In light thereof, pacing stimulus, as understood by those of skill in the art, is applied at a chosen time during a patient's cardiac rhythm. Particularly, there are periods when pacing stimulus is not applied because the heart is unprepared to receive and respond to such a pacing stimulus, known as the refractory period.

Independent device claims 1, 5-7, 17, 21-23, 33, and 37-39 each recite power supplies and/or other circuitry for providing anti-bradycardia pacing stimulus including a capacitor subsystem for storing the anti-bradycardia pacing energy. In light of the above remarks, Kroll et al. do not appear to suggest that this type of pacing stimulus is supplied. Instead, contraction is forced in the heart muscle, rather than a self propagating depolarization wave that simply exceeds rheobase sufficiently to enable the heart to contract under its own power. Indeed, Kroll et al. distinguish pacing from that which Kroll et al. teaches, as noted above, rendering pacing nonobvious due to Kroll et al.'s teaching away. Therefore, each of claims 1, 5-7, 17, 21-23, 33, and 37-39, along with dependent claims 2-4, 8-16, 18-20, 24-32, 34-36, and 40-48, are believed to be patentable over Kroll et al. using either §102 or §103 standards.

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Likewise, each of independent method claims 49 and 53-55 recite generating, storing, and delivering anti-bradycardia pacing energy/stimulus. For reasons similar to those noted with respect to the device claims, claims 49 and 53-55, as well as dependent claims 50-52 and 56-69, are believed to be patentable over Kroll et al. using either §102 or §103 standards.

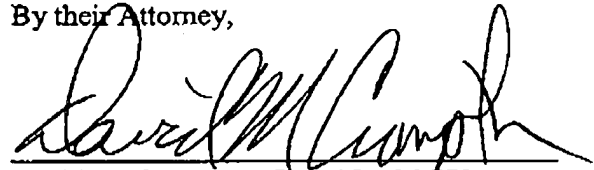
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

Date: 12/17/04



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